Impact of Nagoya protocol on flavour research

ROBIN CLERY and Klaus Gassenmeier
Givaudan AG, Ueberlandstrasse 138, 8600 Dübendorf, Switzerland.

Abstract

On 12th October 2014 the *Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization* came into effect on being ratified by the 50th party. So, three years after ratification, what has happened and what impact can be expected on commercially orientated flavour research?

The overall aims and intentions of the Nagoya Protocol are relatively clear in principle; researchers who obtain biological materials from a Nagoya country with ABS legislation in place, and develop and launch a new ingredient based on that research, now have an obligation to establish a benefit sharing agreement with the provider.

However, the specific national laws and regulations are often complex and unclear. On the provider side, where national access legislation exists it is variable in its scope and application while the official processes and documentation are still evolving in many countries. On the user side, the EU has enacted the first compliance legislation and is currently working on the guidance documentation and the processes for making the declarations as required by the legislation.

The main impact for those involved in flavour research appears to be more paperwork, a need to carry out additional due diligence concerning the origin of natural materials, and in some cases additional agreements or contracts when obtaining biological materials for use in research programs. At present there are many more questions than answers and most of the activity is in the realm of industry associations and corporate legal departments but as the obligations under the EU legislation become clearer it is now beginning to impact at the research laboratory level.

Introduction

For most of the long history during which mankind has harvested the wealth of nature, the natural resources of the planet could be claimed and used by those who invested the time and effort to obtain and develop them. Throughout the 17th to 19th century, as colonialization and international trade developed, botanic gardens and agricultural experimental stations were established around the world to assist the transfer of valuable species to alternative locations where they could be developed and traded. The benefit of this trade was mostly gained by those doing the trading such as the French, British, Portuguese and Dutch through their respective East India companies. Rubber trees were relocated from Brazil to Malaysia, vanilla relocated from Mexico to Madagascar, tea, coffee and cocoa redistributed to plantations worldwide, and this was encouraged by the governments of the time. An early example is that of Pierre Poivre, who in 1770 as Governor of Mauritius established the botanic garden there and obtained clove, nutmeg, pepper and other plants from the Spice Islands, now Maluku islands in Indonesia to be grown in Mauritius for the benefit of France. When plants were relocated, whether purchased or plundered, there was often little benefit for the local communities, although some colonial enterprises did establish local plantations and trading posts that enhanced the wealth of at least some of the local population.

Things changed significantly in 1992 with the “Rio Earth Summit”, a landmark United Nations conference covering many topics related to sustainable development and

B. Siegmund & E. Leitner (Eds): Flavour Sci., 2018, Verlag der Technischen Universität Graz
DOI: 10.3217/978-3-85125-593-5-64, CC BY-NC-ND 4.0

the economic development of natural resources. At the Rio conference the Convention on Biological Diversity (CBD) was opened for signature and it came into force in 1993[1]. Among many other things, this established that countries could assert sovereign rights over the '*genetic resources'* found in their territory. Thus biological resources now belong to the country in which they are found and, following the principles of Access and Benefit Sharing (ABS) established by the CBD, anyone wishing to develop those biological resources for commercial gain should negotiate a benefit sharing deal with the country of origin. Although the principles had been established, it has taken many years of discussion and negotiation for further treaties to evolve such as the Bonn Guidelines (2002) and the Nagoya Protocol (2010) which define the principles of Access and Benefit Sharing in more detail. These are international treaties and, as such, have no legal bearing on individuals, companies or institutions. It is up to the countries that are parties to these conventions to establish their own policy measures and enact their own legislation to address these principles, thus the application of the Nagoya Protocol can be very different in different countries.

The Nagoya protocol

To give it its full title, '*The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity*' was adopted at the Conference of the Parties in 2010 in Japan and finally came into force on 12th October 2014 with the 50th signatory [2]. The full text is available online [3].

From the perspective of a '*User'*, the principle of the Nagoya protocol can be summarised as;

"If genetic resources or traditional knowledge associated with genetic resources are obtained from a country that is a party to the Nagoya protocol for the purposes of research and development, then some of the benefits from its subsequent commercialisation should be shared with the provider."

The protocol sets out the regulatory, administrative and policy measures to be undertaken by the parties at national level, and also establishes the concept of national focal points and an international clearing-house mechanism [5] for the exchange of information relating to access and benefit sharing in each country.

One of the challenges in understanding the scope and application of the Nagoya protocol comes in the interpretation of the limited definitions in Article 2 of the CBD and Article 2 of the Nagoya protocol [6,3]. The following is a simplified interpretation of the words used in the title of the protocol:

Access: Obtaining genetic resources or traditional knowledge *in situ*, or from *ex situ* collections or through trade. Requires Prior Informed Consent (PIC)

Genetic resources: Plants, animals, microbes, their DNA/RNA, and extracts made from them.

Equitable sharing: Mutually Agreed Terms (MAT), benefit sharing agreement.

Benefits: Monetary or non-monetary; payments, shared results and IP, community projects, etc.

Utilization: Carrying out Research & Development.

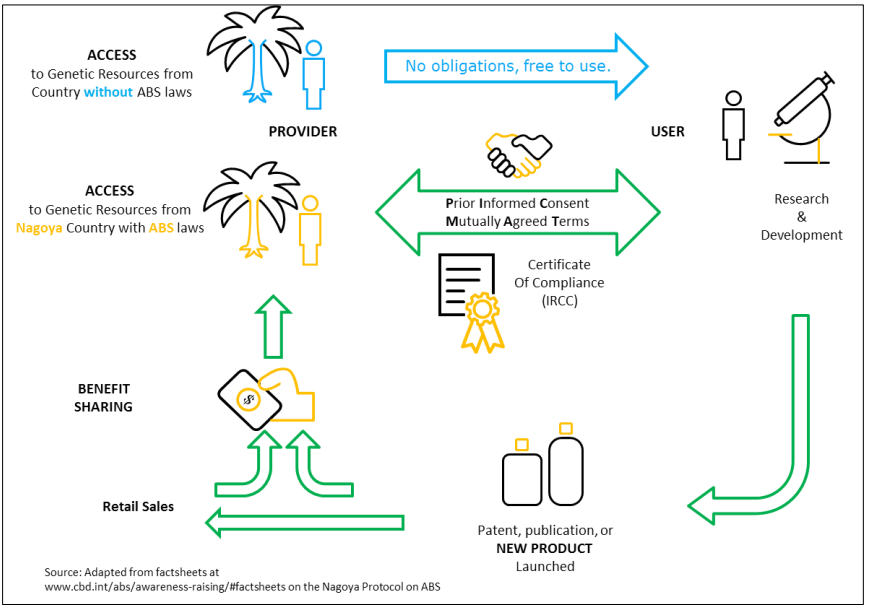

Figure 1: Principles of access and benefit sharing [4]

There are some specific exceptions, notably the exclusion of human genetic resources, certain pathogenic organisms, and genetic resources covered by other instruments such as the ITPGRFA for crop plants [7].

Currently, 32 '*Provider'* countries have registered some form of legislative, administrative or policy measures on the clearing-house website [5] and others are in the process of developing their legislation. So far, only the European Union has enacted compliance legislation as a '*User'* of genetic resources and it in turn transfers the obligations for administering the measures to its member states. The registration to date of over 100 internationally recognised certificates of compliance (IRCC) on the clearing house website is evidence that the system is beginning to function, and there are certainly many more ABS agreements that have been successfully concluded in some form or other.

The EU Regulation EU-ABS 511 / 2014

Since the EU represents countries that are mainly '*Users'* rather than '*Providers'* of genetic resources it has enacted compliance legislation but not access legislation. The regulation: *EU-ABS 511 / 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union* [8] came into force in 2014 and applies, along with the Nagoya Protocol from 12th October 2014. The text contains several cumulative requirements, and is also based on definitions that are open to interpretation, but which can be summarised as:

If genetic resources or traditional knowledge associated with genetic resources are obtained …by a user carrying out R&D in the EU

…from a country that is party to the Nagoya Protocol with ABS laws in place

…after 12th Oct 2014,

then the user is required to comply with the legislation in the country of origin.

The user should carry out due diligence to determine if the EU ABS regulations and any laws in the country of origin apply. If the regulations apply, a declaration of the due diligence should be submitted to the EU via the 'DECLARE' system which is currently in development. The regulations identify two trigger points at which the due diligence should be carried out and a declaration made; on receiving funding for the work, and on launching a new product on the market in the EU. And by default there is a trigger point on '*Access'* to the genetic resources or traditional knowledge.

The EU has published a general Guidance Document [9] to assist the interpretation of the regulations and is in the process of preparing Sectorial Guidance Documents for each of 7 sectors; Cosmetics, Animal Breeding, Plant Breeding, Biocontrol, Pharmaceuticals, Food and Feed, Biotechnologies, and also for Upstream Actors including collections and research institutions. These guidance documents have been prepared in consultation with relevant industries through their associations which, for the purposes of the flavour industry, includes IOFI, IFRA, EFFA, and EU SpecialityFoodIngredients. The guidance documents will provide more specific interpretations of the scope and application of the regulations but they are not themselves legally binding. There are an increasing number of law firms and lawyers specialising in Biodiversity Law and a variety of NGOs that champion the cases of the providers as well as facilitating benefit sharing agreements between providers and users. The Union for Ethical Biotrade (UEBT) is one such organisation that is well established in the flavour, fragrance and cosmetics area.

There are several unresolved issues which are still subject to on-going discussions at various levels right up to the UN. Notably the topic of Digital Sequence Information (DSI) which is currently understood to be outside the scope of Nagoya, but certain countries cover this in their national legislation. It is being discussed and reviewed by many interested parties including UN, ITPGR, WHO, ICC [10] etc., and is on the agenda for the CBD conference of the parties in 2018.

An unresolved topic with direct impact on researchers is the definition of research and development itself. This is of critical importance, since it is the act of carrying out R&D on a genetic resource than triggers the need to carry out due diligence. However, it is not clear which activities fall within the definition. The proposed definitions are based on the Frascati Manual of the OECD [11] and the activities under discussion include, among others, routine QC tests, screening to de-select material from further study, and toxicological tests for regulatory purposes.

The concept and definition of "derivatives" has been a point of much discussion since the outset. It is defined in article 2e) of Nagoya as "*…a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources…"*, and referred to in the definition of utilization, but not mentioned elsewhere. The EU guidance document [8] interprets this to mean that a derivative is in scope when accessed in combination with the genetic resource from which it is derived. So it may be inferred that "isolated derivatives" such as many food and flavour ingredients purified from plants or animals such as proteins, fats & oils, essential oils and flavour extracts would be out of scope when accessed without any associated access to their original genetic resources.

As it stands in 2017, the guidance from the EU and the processes and systems of the competent authorities are still very much in development, nonetheless, it is slowly becoming clearer which research activities involving genetic resources fall in scope and what, if any, legal obligations apply.

Implications for flavour research

Biodiversity and genetic resources are important for flavour research and it is our responsibility as scientists to use them wisely, and as an industry to carry out commercial developments ethically.

The landscape around the use of natural biological materials as a starting point for research projects in the EU is changing. With the gradual introduction of both access legislations in provider countries and compliance legislation in user countries the act of obtaining biological material for an R&D project may now carry certain obligations.

For anyone involved in obtaining biological materials for a research project, this means ensuring that the relevant checks concerning ABS legislation in the country of origin are carried out and documented, and that any corresponding requirements are met. For research institutions or collections of biological resources this may relate to the transfer of relevant information to subsequent users. For commercial and applied research activities this may involve some form of benefit sharing with the original provider, or the transfer of relevant information to subsequent retailers of the new product developed from their research.

For flavour and fragrance houses with their own R&D departments and for traders obtaining new products from abroad, this will mean more checks and more paperwork for everyone along the supply chain, but not necessarily more constraints on the scope or quality of flavour research that can be successfully carried out in the EU.

References

1. History of The Convention on Biological Diversity. https://www.cbd.int/history accessed Sept.2017
2. The Nagoya Protocol on Access and Benefit Sharing, www.cbd.int/abs accessed Sept.2017
3. Full Text of Nagoya Protocol. https://www.cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf
4. ABS Information Kit. www.cbd.int/abs/awareness-raising/#factsheets on the Nagoya Protocol on ABS. accessed Sept.2017
5. The ABS Clearing House. https://absch.cbd.int/ accessed Sept.2017
6. The Text of the CBD. https://www.cbd.int/doc/legal/cbd-en.pdf
7. International Treaty on Plant Genetic Resources for Food and Agriculture. http://www.fao.org/plant-treaty/en/
8. EU ABS Regulation 511/2014. http://ec.europa.eu/environment/nature/biodiversity/international/abs/legislation_en.htm
9. EU Guidance Document for regulation no. 511/2014. http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2016.313.01.0001.01.ENG
10. ICC Position Paper on DSI. https://cdn.iccwbo.org/content/uploads/sites/3/2017/05/ICC-IP-position-paper-on-digital-sequence-information.pdf
11. The Frascati Manual 2015. OECD. http://www.oecd.org/innovation/inno/frascati-manual.htm